UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO EXCLUDE THE TESTIMONY OF DRS. DAVID SCHWARTZ, DAVID KATZ, LEE-JEN WEI, MINDY KURZER, RICHARD GOODMAN, AND DAVID GORTLER

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Plaintiffs Federal Trade Commission and the People of the State of New York by Letitia James, Attorney General of the State of New York, respectfully submit this Memorandum of Law in support of their Motion to Exclude the Testimony of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler. Each of these experts seeks to offer testimony in support of Defendants in this matter, but the testimony they propose to offer is inappropriate for the jury to hear and should be excluded.

I. INTRODUCTION

Defendants seek to present to the jury six expert witnesses offering inadmissible evidence: legal opinions, opinions based on unreliable methods or outside the scope of their expertise, testimony that is irrelevant to this case, and testimony that would only confuse the issues, mislead the jury, waste the Court's time, or cause unfair prejudice. Because such evidence does not satisfy Federal Rules of Evidence 402, 403, and 702, and *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579 (1993), Plaintiffs request that the Court exercise its gatekeeping function and exclude it, including any reliance on, references to, or arguments based upon it, at trial.

In this case, Plaintiffs allege that Defendants deceptively represented that their Prevagen products: (1) improve memory; (2) improve memory within 90 days; (3) reduce memory problems associated with aging; and (4) provide other cognitive benefits, including, but not limited to, healthy brain function, a sharper mind, and clearer thinking ("Challenged Efficacy Claims"). (Compl. (ECF No. 1) ¶¶ 36-38, 42-45). Plaintiffs also allege that Defendants deceptively represented that such claims for Prevagen products are clinically shown ("Challenged Clinically Proven Claims" and collectively with the Challenged Efficacy Claims, "Challenged Claims"). (*Id.* ¶¶ 39-41, 42-45). The core legal questions are whether Defendants have "competent and reliable scientific evidence" to substantiate the Challenged Efficacy Claims

and whether they have the level of evidence they claimed to have for the Challenged Clinically Proven Claims, specifically a well-designed, randomized, controlled, double-blinded human clinical trial ("RCT"). None of Defendants' experts opines on whether Defendants have substantiated the Challenged Clinically Proven Claims with the RCT that Defendants widely touted in their national advertising. In fact, Defendants' experts seem to be unaware of the Challenged Clinically Proven Claims. As to the Challenged Efficacy Claims, Defendants' experts fail to opine on the scientific standards experts in the relevant fields believe constitute competent and reliable scientific evidence for memory- and cognitive-improvement claims. Instead, Defendants' experts offer impermissible and erroneous legal opinions that are predicated on a fundamental misunderstanding of FTC law and guidance and irrelevant Food and Drug Administration ("FDA") laws, regulations, and guidance; actions taken by FDA with respect to the drug Aduhelm; and actions taken by other dietary supplement marketers.

Defendants' experts also opine on issues for which they are not qualified and proffer various conflicting and unreliable statistical theories for Defendants' primary human clinical study, the Madison Memory Study. First, Dr. David Katz lacks the qualifications to conduct and interpret an econometric re-analysis of the Madison Memory Study, and Dr. Mindy Kurzer is unqualified to offer opinions relating to cognition and memory. Additionally, Dr. Lee-Jen Wei offers an incomplete and unreliable statistical analysis by failing to apply his own alternative statistical methodology to the Madison Memory Study, and therefore, his statistical analysis should be excluded in its entirety. Finally, Dr. Kurzer evaluates the Madison Memory Study's results using a method based on her logic or common sense, which is not subject to any standards, and should be excluded.

Defendants also propose to present speculative expert testimony regarding potential mechanisms of action for Prevagen – i.e., theories about how Prevagen *might* be able to have some effect on human memory or cognition. Defendants' experts fail to adequately tie their speculation to specific characteristics of Prevagen's active ingredient, apoaequorin. Defendants' experts advance a broad array of theories about Prevagen's mechanism of action, largely based on how other substances that are not Prevagen work. Yet, for the most part, they do not tie their testimony to the specifics of this case – i.e., apoaequorin, which is an active ingredient in Defendants' products. This testimony is therefore unreliable, irrelevant, and, because it is likely to unduly confuse and influence the jury, prejudicial. Additionally, portions of the testimony offered by Drs. Richard Goodman and David Gortler venture well outside their expertise and should be excluded on that basis.

II. LEGAL STANDARDS FOR THE ADMISSIBILITY OF EXPERT TESTIMONY

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Daubert explains that "[t]he adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. Thus, "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) ("*Daubert II*"). "Proposed testimony must be supported by appropriate validation – *i.e.*, 'good grounds,' based on what is

known." *Daubert*, 509 U.S. at 590. Proffered testimony "doesn't become 'scientific knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive." *Daubert II*, 43 F.3d at 1315-16. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to the existing data only by the *ipse dixit* of the expert." *GE v. Joiner*, 522 U.S. 136, 146 (1997). Indeed, a "court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id*.

Under Rule 702, the proposed testimony must "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. of Evid. 702. This requirement is "akin to the relevance requirement of Rule 401," but also requires expert testimony to have a "valid scientific connection to the pertinent inquiry as a precondition of admissibility." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 540 (S.D.N.Y. 2004); *see also* Fed. R. Evid. 401 ("Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action."). Stated otherwise, to be admissible, there must be a proper "fit" between proffered expert testimony and the issues to be resolved at trial. *Daubert*, 509 U.S. at 591. "'Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.'" *City of New York v. FedEx Ground Package Sys., Inc.*, No. 13-CIV-9173, 2018 WL 4961455, at *6 (S.D.N.Y. Oct. 15, 2018) (stating that the issue was whether defendant knowingly shipped cigarettes, and expert testimony on the public health effect of defendant's conduct did not help answer the factual issues of the case) (quoting *Daubert* , 509 U.S. at 591).

The trial court "has a 'gatekeeping function' under Rule 702 – it is charged with the 'task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the

task at hand." *Amorgianos v. Amtrak*, 303 F.3d 256, 265 (2d Cir. 2002) (citing *Daubert*, 509 U.S. at 597). "While the proponent of expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements of Rule 702 are satisfied, the district court is the ultimate 'gatekeeper.'" *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007) (citations omitted). The objective of a trial judge's gatekeeping requirement is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). "Thus, when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos*, 303 F.3d at 266 (citations omitted).

This Circuit is in accord with other circuits in requiring exclusion of expert testimony that expresses a legal conclusion. *See, e.g.*, *Hygh v. Jacobs*, 961 F.2d 359, 363 (2d. Cir. 1992); *United States v. Scop*, 846 F.2d 135, 140 (2d Cir. 1988); *Marx & Co. v. Diners' Club, Inc.*, 550 F.2d 505, 510-12 (2d Cir. 1977); *Torres v. County of Oakland*, 758 F.2d 147, 150 (6th Cir. 1985); *Strong v. E.I. DuPont de Nemours Co.*, 667 F.2d 682, 685-86 (8th Cir. 1981). "Generally, the use of expert testimony is not permitted if it will 'usurp either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it.'" *United States v. Duncan*, 42 F.3d 97, 101 (2d Cir. 1994) (citations omitted).

Finally, under Rule 403, expert testimony – even if relevant – must be excluded if "its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, or wasting of time." Fed. R. Evid. 403. Indeed, in light of the difficulty a jury may have in evaluating expert testimony, and the "unique weight" a jury

may assign to such testimony, Rule 403 plays a "uniquely important role" in a court's determination of whether to admit expert testimony. *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005). Because expert testimony "can be both powerful and quite misleading because of the [jury's] difficulty in evaluating it," courts must exercise "more control over experts than over lay witnesses." *Daubert*, 509 U.S. at 595 (internal quotation marks omitted).

III. DEFENDANTS' EXPERTS OFFER IRRELEVANT AND ERRONEOUS LEGAL CONCLUSIONS THAT ARE OUTSIDE THEIR EXPERTISE AND WITHIN THE PURVIEW OF THE COURT TO DECIDE

Three of Defendants' experts, Drs. David Schwartz, David Katz, and Lee-Jen Wei, none of whom is a legal expert, seek to recast the well-established FTC and New York law governing this case by offering improper and erroneous legal opinions on the appropriate standard of evidence for the Challenged Claims about Prevagen. For years, Defendants have flaunted their purported RCT – the Madison Memory Study – as scientific support for their memory- and cognitive-improvement claims in their national advertising campaign to distinguish themselves from their competitors. Defendants' experts, however, refuse to evaluate Defendants' research according to the level of evidence Defendants claimed to have, as required by FTC and New York precedent.

Instead, Drs. Schwartz, Katz, and Wei base a substantial portion of their substantiation opinions on their personal – and mistaken – legal interpretations of FTC law and guidance and irrelevant FDA laws, regulations, guidance, and drug approvals, rather than any scientific expertise. Indeed, the legal conclusions offered by Drs. Schwartz, Katz, and Wei are *not* based on any evaluation of what type of evidence experts in the relevant fields of memory, cognition, and clinical trials would require. These experts also fail to consider whether the purported RCT and non-RCT studies Defendants rely upon as substantiation were conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the

relevant field to yield accurate and reliable results. (Graham Decl. (ECF No. 225) Ex. F, *Dietary Supplements: An Advertising Guide for Industry* ("FTC Guidance") at QUI-FTCNY-00189212); *See also FTC v. Alcoholism Cure Corp.*, No. 3:10-cv-266-J-34JTB, 2011 WL 13137951, at *27 (M.D. Fla. Sept. 16, 2011).

The danger of allowing experts to present impermissible legal opinions at trial is compounded in this case by the fact that the legal opinions of Drs. Schwartz, Katz, and Wei are wrong. Drs. Schwartz, Katz, and Wei erroneously maintain that, according to FTC and FDA law, Defendants were not required to have an RCT to substantiate the Challenged Claims and the mere fact that they did, in fact, conduct an RCT greatly exceeds the legal standards required for dietary supplement manufacturers, including Defendants. As discussed below, they are incorrect. The Court should exercise its gatekeeping function to exclude the legal opinions of Drs. Schwartz, Katz, and Wei, all of which present the risk of unfair prejudice, confusion of the issues, misleading the jury, and undue delay.

A. Drs. David Katz, David Schwartz, and Lee-Jen Wei Offer Inadmissible Legal Opinions

The reports and testimony of Drs. David Katz, David Schwartz, and Lee-Jen Wei are replete with legal opinions about FDA laws, regulations, guidance, and drug approvals, which are inapplicable to this action, FTC law and guidance, and what they consider to be differences in the legal standards for marketing claims for dietary supplements versus drugs. Rather than explaining what experts in their respective fields would consider to be competent and reliable scientific evidence for Defendants' memory- and cognitive-improvement claims, as required by FTC case law, all three experts purport to interpret FTC and FDA law and opine on what they believe the FTC said and did not say in *Dietary Supplements: An Advertising Guide for Industry* ("FTC Guidance").

Drs. Schwartz, Katz, and Wei are not lawyers, and as such, they are unqualified to offer legal opinions. More importantly, their personal legal opinions are inappropriate for expert testimony. Opinions about the appropriate legal standard are generally impermissible, as they do not constitute "scientific knowledge," do not have a reliable basis in any scientific discipline, and impermissibly intrude upon the duty of the Court to instruct the jury with regard to the applicable law. *See In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 469 (S.D.N.Y. 2018).

Dr. Schwartz, a neuroscientist by training, never opines on the scientific standards that neuroscientists in his field would require to substantiate Defendants' memory- and cognitive-improvement claims. Instead, he states that he reviewed Defendants' research in the context of FDA's Dietary Supplement Health and Education Act of 1994 ("DSHEA"), which has no bearing in this case, and the FTC Act, and concludes that "the Challenged Claims do not meet the definition of disease claims as defined by the Food and Drug Administration. Thus, the level of evidence that would be necessary for a drug is unnecessary in this context." (Graham Decl. (ECF No. 225) Ex. W, Schwartz Aff. Report ¶¶ 7, 10.) Dr. Schwartz proffers a similarly irrelevant legal conclusion that the "Prevagen product packaging is in compliance with the Food and Drug Administration Code of Federal Regulations Title 21." (*Id.* ¶ 9.) He devotes an entire section in his rebuttal report to the "Level of Evidence Required for Dietary Supplement Manufacturers to Substantiate Structure-Function Claims," renders his own interpretation of FDA's regulatory framework for dietary supplements and drugs, discusses the FDA's recent approval of the prescription drug Aduhelm, which is intended for patients with Alzheimer's disease, offers generalized views on what he construes to be the different legal standards for dietary supplements and drugs, compares Prevagen to other dietary supplement marketers, and

rejects the notion that an RCT can ever be required to substantiate memory- and cognitive-improvement claims for a dietary supplement. (Graham Decl. (ECF No. 225) Ex. X, Schwartz Rebuttal Report ¶¶ 3-4, 8-9, 11-26, 46, 49, 50.)

Dr. Katz, an internal medicine doctor, similarly offers opinions in the context of FDA's DSHEA, discusses FDA's approval of Aduhelm, and states that he reviewed the FTC Guidance "to determine what the FTC has told the dietary supplement industry in terms of what constitutes a reasonable basis for claims relating to supplements." (Graham Decl. (ECF No. 225) Ex. P, Katz Rebuttal Report ¶¶ 2, 10, 31-36.) He, too, devotes an entire section of his rebuttal report to "The Appropriate Standard of Review for Dietary Supplement Products," faults Plaintiffs' experts for not "acknowled[ing] that the standards for claim substantiation for drugs and dietary supplements are distinct," and concludes that the FTC Guidance "does not require human clinical trials." (*Id.* ¶¶ 2, 6, 18-30.) Dr. Katz completely overlooks the obvious flaws in Defendants' research and faults Plaintiffs' experts for "devoting much of their expert attention to the caliber of [Defendants'] RCT" because in his view, "the mere fact that Quincy conducted a randomized clinical trial in humans and obtained results *suggesting* a clinical benefit in a defined population already greatly exceeds the required standard to market a dietary supplement under [FDA's] DSHEA and the FTC's own Guidance." (*Id*. ¶¶ 21-23, 26, 29) (emphasis added).)

Finally, Dr. Wei, a biostatistician, states that he reviewed the FTC's Guidance and claims that it makes clear that "randomized, clinical trials are not required" for dietary supplements. (Graham Decl. (ECF No. 225) Ex. Z, Wei Rebuttal Report ¶¶ 10, 13-17, 51.) At his deposition, Dr. Wei repeatedly relied on what he believed the FTC did not say in the FTC Guidance as a basis for his analysis. (*See, e.g.*, Matuschak Decl. Ex. C, Wei Tr. at 55:15 – 65:23.)

Whereas Drs. Schwartz, Katz, and Wei may be uniquely qualified by experience to assist the jury in evaluating Defendants' substantiation according to the scientific standards of their fields, they are not qualified to compete with the Court in instructing the jury. *See Hygh*, 961 F.2d at 364. It is therefore impermissible to allow them to state their opinions on the law of the forum. *See Marx & Co.*, 550 F.2d at 510 (citing *Loeb v. Hammond*, 407 F.2d 779 (7th Cir. 1969)).

Defendants' experts' opinions about the evidence necessary to substantiate the challenged claims, as well as the sufficiency of Defendants' proffered substantiation, are based not on science, but on their interpretation of the law. Their conclusions are *not* based on any evaluation of what type of evidence experts in the relevant fields of memory and cognition would require. As a critical step of their reasoning is based not on the scientific method but on their personal legal interpretations, Defendants' experts' substantiation analysis is unreliable and inadmissible. *See Amorgianos*, 303 F.3d at 267. Plaintiffs therefore request that the Court exclude any testimony by these experts' as to their perceived notions about the appropriate legal standard that applies in this case.

B. The Opinions of Drs. Schwartz, Katz, and Wei Relating to FDA Are Irrelevant

Not only do Defendants' experts offer improper legal opinions, but their opinions on FDA's evidentiary standards are not relevant. The degree of regulation that Prevagen or any other dietary supplement would be subjected to by the FDA does not apply to any of the issues of this case. *See Bristol-Myers Co. v. FTC,* 738 F.2d 554, 559 (2d Cir. 1984) ("Insofar as FDA requirements and regulations are concerned, they simply do not govern this case."); *see also Thompson Med. Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986) (stating that *Bristol-Myers* made it quite clear that FDA requirements and regulations were a different regulatory scheme and did

not govern an FTC case); *FTC v. Lunada Biomedical*, No. CV-15-3380-MWF, 2015 WL 12911515, at *4-5 (C.D. Cal. Sept. 23, 2015) (noting that FDA requirements and regulations did not apply even when the product at issue was a dietary supplement); *FTC v. Wellness Support Network, Inc.*, No. 10-4879, 2013 WL 5513332, at *10 (N.D. Cal. Oct. 4, 2013) (FDA classification of a product as a drug or medical food was irrelevant; granting FTC's motion to exclude testimony of expert as it did not constitute "scientific knowledge"). This case is not brought under any statute or rule enforced by the FDA and does not involve the FDA's regulatory process for drugs generally or for Aduhelm specifically. Likewise, evidence comparing Defendants to other dietary supplement companies that market different products simply has no bearing on whether the Challenged Claims were supported by competent and reliable scientific evidence. Courts have excluded expert evidence that does not relate to any issue to be resolved at trial. *See, e.g.*, *United States v. Aiyer*, 33 F.4th 97, 123, 126 (2d Cir. 2022) (affirming the exclusion of expert testimony on reasonableness and procompetitive benefits of the conduct because the conduct was *per se* unreasonable and thus the testimony was not relevant to any issue in the case); *Town & Country Linen Corp. v. Ingenious Designs LLC*, No. 18-cv-5075, 2022 WL 2757643, at *3 (S.D.N.Y. July 14, 2022) (stating that expert testimony that "relates only to issues that are no longer in the case after the Court's summary judgment ruling . . . will be excluded as no longer relevant to any issue in the case").

With no probative value, evidence about FDA, Aduhelm, and other dietary supplement marketers would only serve to mislead the jury, confuse the issues, cause unfair prejudice, and lead to undue delay. *See United States v. Gatto*, 986 F.3d 104, 117-18 (2d Cir. 2021) (affirming the district court's exclusion of evidence because it was not helpful and would only serve to entice the jury to base its decision on an improper defense); *In re Fosamax Prods. Liab. Litig.*,

645 F. Supp. 2d 164, 198 (S.D.N.Y. 2009); Fed. R. Evid. 403. It is nothing more than an attempt to conflate what is required under FTC or New York laws with FDA law and lead the jury to consider facts that do not go to any issues in the case. Plaintiffs therefore request that all such opinions relating to FDA's DSHEA, other FDA statutes, regulations, guidance, or drug approvals, and the actions of other dietary supplement manufacturers be excluded in their entirety.

C. The Erroneous Opinions of Drs. Schwartz, Katz, and Wei About FTC Law and Guidance Increase the Likelihood of Confusing the Jury

The view expressed by Drs. Schwartz, Katz, and Wei that under FTC law and guidance, an RCT is not required to substantiate health claims for a dietary supplement is simply wrong. In applying the FTC's competent and reliable scientific evidence standard, courts have regularly concluded that an RCT was required to substantiate claims based on expert evidence, including for dietary supplements. *See, e.g.*, *POM Wonderful LLC v. FTC*, 777 F.3d 478, 505 (D.C. Cir. 2015); *Daniel Chapter One v. FTC*, 405 F. App'x 505, 506 (D.C. Cir. 2010) (noting that there was nothing "unreasonable about the specific type of basis required by the Commission, namely, 'competent and reliable scientific evidence' including clinical trials with human subjects"); *FTC v. Roca Labs, Inc.*, 345 F. Supp. 3d 1375, 1381, 1387-89 (M.D. Fla. 2018); *FTC v. NPB Adver., Inc.*, 218 F. Supp. 3d 1352, 1359 (M.D. Fla. 2016); *FTC v. COORGA Nutraceuticals*, 201 F. Supp. 3d 1300, 1309 (D. Wyo. 2016) (finding that an RCT is the requisite level of substantiation); *Alcoholism Cure Corp.*, 2011 WL 13137951, at *39 (noting that many courts have "embrac[ed] the placebo-controlled, double-blind clinical study as the most basic and fundamental requirement for scientific validity and reliability to support health-related claims (including dietary supplements)"); *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1202 (N.D. Ga. 2008); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 303-04 (D.

Mass. 2008) (stating that it is "well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims"); *FTC v. Braswell*, No. CV 03-3700, 2005 WL 4227194, at *10 (C.D. Cal. Sept. 27, 2005) (listing cases where "courts . . . have found or upheld that double-blind, placebo controlled studies are required to provide adequate substantiation for various efficacy claims, including claims for dietary supplements").

In addition, contrary to the opinions expressed by Drs. Schwartz, Katz, and Wei, the FTC has not told the dietary supplement industry in its Guidance that an RCT is unnecessary to substantiate health claims such as the Challenged Claims. (Graham Decl. (ECF No. 225) Ex. X, Schwartz Rebuttal Report ¶¶ 14, 16-17, 21, 49-50; Graham Decl. (ECF No. 225) Ex. P, Katz Rebuttal Report ¶¶ 20-21, 23; Graham Decl. (ECF No. 225) Ex. Z, Wei Rebuttal Report ¶¶ 13-16, 51.) All three of Defendants' experts cherry pick those portions of the FTC Guidance that serve their opinions and ignore those portions that contradict their opinions. For instance, they focus on the statement that "[t]he FTC's substantiation standard is a flexible one that depends on many factors" but gloss over the statements that the "FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with 'competent and reliable scientific evidence,'" which is "the same standard the FTC applies to any industry making health-related claims." (Graham Decl. (ECF No. 225) Ex. F, *Dietary Supplements: An Advertising Guide for Industry* ("FTC Guidance") at QUI-FTCNY-00189212.) They also disregard the statement that there are "some principles generally accepted in the scientific community to enhance the validity of test results[,]" including that "a study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results," "[s]tatistical significance of findings is also important," and "[t]he results should also translate into a meaningful benefit for consumers." (*Id.*at QUI-FTCNY-00189215.)

More importantly, all three experts overlook those portions of the FTC Guidance that directly relate to the facts of this case. The FTC Guidance clearly cautions that "[i]f an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate." (*Id.* at QUI-FTCNY-00189212.) In other words, since Defendants claimed to have an RCT, they were required to have that level of support.

Not only are Defendants' interpretations of FTC law and Guidance inadmissible legal conclusions, but their legal interpretations are erroneous, thereby increasing the danger of confusion of the issues, misleading the jury, and undue delay. Therefore, Plaintiffs request that the Court exclude such opinions and confine these experts to opining on matters that are within the scope of their expertise.

IV. DR. KATZ LACKS EXPERTISE TO TESTIFY ABOUT A RE-ANALYSIS OF DEFENDANT'S PRIMARY HUMAN CLINICAL STUDY USING THE SEEMINGLY UNRELATED REGRESSIONS ("SUR") ECONOMETRIC MODEL

Defendants' expert, David Katz, M.D., opines that a re-analysis of the Madison Memory Study, conducted years after the study was completed, purportedly using an econometric model – seemingly unrelated regressions ("SUR") – "produces decisively significant results for those study participants without cognitive impairment." (Graham Decl. (ECF No. 225) Ex. O, Katz Aff. Report ¶¶ 35-37.) Dr. Katz is the only expert Defendants proffer to opine on the so-called SUR re-analysis of the Madison Memory Study. Because Dr. Katz: (1) is not personally qualified to conduct or interpret a SUR analysis, (2) is merely parroting the opinions of Dr. Howard Beales, who conducted the analysis, and (3) is unable to recognize that Dr. Beales did not in fact conduct the SUR analysis Dr. Beales states he conducted, Plaintiffs seek to exclude Dr. Katz's testimony and all evidence relating to Dr. Beales' analysis.

"[A] proffered expert may not simply pass off as [his] own, or serve as a vehicle for presenting, the opinions of others in subjects on which the proffered expert is not personally qualified." *Hart v. BHH, LLC*, No. 15-CV-4804, 2018 U.S. Dist. LEXIS 12131, at *23 (S.D.N.Y. July 19, 2018); *see also Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 664-66 (S.D.N.Y. June 15, 2007) (excluding testifying expert's testimony where he relied solely on consulting expert for statistical analysis, because testifying expert was not qualified to conduct or interpret statistical analysis and thus served as a mouthpiece for that consultant). Indeed,

> [a] theoretical economist, however able, would not be allowed to testify to the findings of an econometric study conducted by another economist if he lacked expertise in econometrics and the study raised questions that only an econometrician could answer. If it were apparent that the study was not cut and dried, the author would have to testify; he could not hide behind the theoretician.

Dura Auto. Sys. v. CTS Corp., 285 F.3d 609, 613 (7th Cir. 2002).

But this is precisely what Defendants seek to do here – present Dr. Beales' opinions through Dr. Katz, who lacks the necessary qualifications to opine on Dr. Beales' flawed econometric analysis.

While Dr. Katz, an internal medicine doctor by training, has some experience in biostatistics, he has no experience in econometrics generally or in the SUR model specifically. (Matuschak Decl. Ex. A, Katz Tr. at 29:8 – 30:23.) Even though biostatistics and econometrics share a common statistical foundation, the two fields are distinct specialties with their own faculties and degree programs at the graduate level. As such, expertise in biostatistics does not on its own qualify as expertise in econometrics. Dr. Katz's testimony clearly established his lack of familiarity with the SUR model and his inability to determine how Dr. Beales' re-analysis of the Madison Memory Study was conducted and to independently interpret the results. Dr. Katz

conceded that, as to the SUR model, he "profess[es to have] no specific expertise in this analytical method," and it is a "technique [he] had never used and do[es] not know intimately." (*Id*. at 206:17-18; 207:3-6.) Dr. Katz further acknowledged that the bases of his opinions about Dr. Beales' re-analysis were his discussions with Dr. Beales, and that those discussions "were about the general utility of the method, what it is used to do. It was certainly not a tutorial in how to conduct [the SUR analysis] independently, but why [Dr. Beales] did it, why [Dr. Beales] thought it was relevant, what results [Dr. Beales], as an expert in the method, thought it produced." (*Id*. at 208:9 – 209:5.) According to Dr. Katz, he "was guided in this particular matter by [Dr. Beales'] expertise." (*Id*. at 209:5-6.)

Dr. Beales' re-analysis is "not cut and dried," and raises questions that only an expert with knowledge in econometrics can answer. *See Dura Auto. Sys.*, 285 F.3d at 613. For example, Dr. Katz's lack of understanding of the SUR model leaves him unable to interpret the F tests on which the purported conclusions of the SUR analysis rest. (Matuschak Decl. Ex. A, Katz Tr. at 206:1-207:25.) Ultimately, due to his lack of expertise, Dr. Katz cannot opine on whether results generated from Dr. Beales' re-analysis indicated that the Prevagen group outperformed the placebo group in the Madison Memory Study. (*See id*. at 207:12-25); *see also Dura Auto. Sys.*, 285 F.3d at 615 (noting that an expert was unqualified in part because he lacked the necessary expertise to determine whether the techniques were appropriately chosen and applied).

Additionally, Plaintiffs' econometrics expert opines that Dr. Beales did not, in fact, conduct a SUR analysis. In other words, the results reported by Dr. Beales were generated by an analysis that is unequivocally not a SUR analysis. (Matuschak Decl. Ex. B, Malaspina Rebuttal Report ¶¶ 10, 30-38, 40-41.) While Dr. Katz emphasizes the advantages of using a SUR model

for the Madison Memory Study because the study's observations – its outcome measures and each participant's scores at each testing interval – are highly correlated with each other, he fails to realize that Dr. Beales erroneously programmed the SUR model to assume that the study's observations were uncorrelated. (*Id*. ¶¶ 11-12, 29-41.) More importantly, Dr. Katz fails to realize that when Dr. Beales' SUR model is corrected to account for the correlations in the study's observations, there is no evidence that Prevagen has a statistically significant effect on cognitive function when compared to a placebo. (*Id*. ¶¶ 39, 42.)

Dr. Katz lacks familiarity with the SUR model and is not qualified to evaluate its results. Therefore, he cannot "testify for the purpose of vouching for the truth of what [Dr. Beales] had told him – of becoming in short [Dr. Beales'] spokesman." *Dura Auto. Sys.*, 285 F.3d at 613. With respect to the SUR re-analysis, Dr. Katz is not an expert but rather Dr. Beales' "mouthpiece," and his testimony should be excluded. *See Louis Vuitton Malletier*, 525 F. Supp. 2d at 665 (citing *Dura Auto. Sys.*, 285 F.3d at 614).

V. DR. WEI'S TESTIMONY IS UNRELIABLE BECAUSE HE FAILED TO APPLY THE STATISTICAL METHODOLOGY HE OPINES IS NECESSARY FOR THE MADISON MEMORY STUDY

Defendants' biostatistics expert, Dr. Lee-Jen Wei, repeatedly criticizes Plaintiffs' memory and cognition expert, Dr. Mary Sano, and Plaintiffs' biostatistics expert, Dr. Janet Wittes, for evaluating whether the Madison Memory Study yielded statistically significant results based on a Type I error rate of 0.05. In Dr. Wei's view, statistical significance is an outdated concept, and, notwithstanding the fact that Defendants used a Type I error rate of 0.05 to determine statistical significance for the Madison Memory Study, Dr. Wei maintains that "using a p-value of 0.05 as a threshold for significance is not appropriate for the Madison Memory Study." (Graham Decl. (ECF No. 225) Ex. Z, Wei Rebuttal Report ¶¶ 18-22, 27, 52.) Dr. Wei purports to offer an alternative statistical method to determine whether Prevagen outperforms

placebo, but he fails to apply the alternative methodology he states is necessary. Because Dr. Wei fails to apply his own stated methodology to the Madison Memory Study, his testimony is unreliable and should be excluded. *Amorgianos*, 303 F.3d at 266-67 (expert's testimony is unreliable when he failed to apply his own stated methodology).

Dr. Wei opines that, rather than "rely on the outdated and meaningless 'bright line' rule of $p<0.05$ to assess the significance of the Madison Memory Study, there is a better and more efficient way to examine the study, which is also consistent with the FTC's 'flexible' standard for dietary supplements." (Graham Decl. (ECF No. 225) Ex. Z, Wei Rebuttal Report ¶ 23.) In Dr. Wei's view, for the Madison Memory Study, "[i]t is important to use the data from nine outcomes all together for making statistical inferences." (*Id*. ¶ 25.) He cites one of his published papers, "Assessment of Treatment Effect With Multiple Outcomes in 2 Clinical Trials of Patients With Duchenne Muscular Dystrophy," wherein he evaluated a study's multiple outcomes simultaneously, rather than as single endpoints, by: (1) for each outcome, calculating the mean change score (the difference in score from the beginning to the end of the study) for the study's treatment group as well as for the control group, (2) for each outcome, calculating the difference in mean change scores between the treatment and control groups and the corresponding confidence interval around this difference, and (3) obtaining a z score for each outcome and then averaging those z scores (z scores provide a standard measurement for each outcome that allows one to compare outcomes that have different units of measurement, as is the case with the Madison Memory Study's outcomes). (*Id*. ¶ 25.) Yet, despite proffering this alternative statistical method to evaluate the Madison Memory Study, Dr. Wei fails to apply it in his analysis of the study.

As to the first two steps in Dr. Wei's proposed statistical method, calculating mean change scores and corresponding confidence intervals, Dr. Wei partially reports data in a way that would not assist the factfinder in determining whether Prevagen outperforms placebo. In Tables 1 and 2 of his rebuttal report, he merely reports the mean scores at Day 90 for each of the study's nine outcomes for the treatment and control groups of the AD8 0-1 and 0-2 subgroups. His analysis stops there. Dr. Wei does not go on to calculate mean change scores for the treatment or control groups (that is, the change in performance between Day 0 and Day 90 for each group), he does not calculate the difference in mean change scores between the treatment and control groups, and he does not construct the corresponding confidence interval around the difference in mean change scores. (*Id*. ¶¶ 25-29, Tables 1-2.)

At his deposition, Dr. Wei conceded that he had the information he needed to calculate the appropriate confidence intervals for each outcome, and that merely comparing the means at Day 90 between the treatment and control groups for each outcome, as he did in Tables 1 and 2 of his report, does not answer the question of whether the Prevagen group outperforms the placebo group. (Matuschak Decl. Ex. C, Wei Tr. at 249:11 – 255:22; 259:13 – 260:20.) In fact, Dr. Wei even acknowledged that had he compared the difference in mean change scores between the treatment and control groups for the AD8 0-1 subgroup on the International Shopping List-Delayed Recall task (one of the outcomes of the Madison Memory Study), his analysis would have shown that the placebo group outperformed the Prevagen group. (*Id*. at 255:23 – 259:4.) Ultimately, Dr. Wei's selective reporting of mean scores at the end of the study (Day 90) for each group in the AD8 0-1 and 0-2 subgroups, with no mention of changes in scores relative to the Day 0 baseline, leaves the factfinder unable to determine whether the Prevagen group

outperforms the placebo group, or vice versa, or whether there is no difference between the groups.

As to the third step of Dr. Wei's proposed statistical method, obtaining a z score for each outcome and then averaging those z scores, Dr. Wei failed to calculate z scores for the outcomes of the Madison Memory Study altogether because, according to him, he was not given access to the study's raw data. (*Id*. at 241:15 – 243:9, 253:11 – 254:24.) Defendants certainly had access to the raw data of the Madison Memory Study, which they conducted in-house (and indeed, Defendants produced such raw data to Plaintiffs), but they chose not to share that data with Dr. Wei. (*Id*. at 249:1 – 250:25; 253:15 – 254:24.)

Dr. Wei's complete failure to make the calculations he identified as being necessary to his analysis demonstrates that his "methodology" for reaching his conclusions about the Madison Memory Study is not based on good statistical grounds. *See Amorgianos*, 303 F.3d at 266-67. He provides no explanation as to whether or how his failure to properly apply his proposed statistical method affected his conclusions about the Madison Memory Study. Instead, he unequivocally concludes: "Based on my review of the totality of the study results across all nine tests, it is my professional opinion that the Madison Memory Study does meet the FTC's competent and reliable evidence standard because Prevagen does have a positive effect on memory and cognition." (Graham Decl. (ECF No. 225) Ex. Z, Wei Rebuttal Report ¶ 30.) In light of Dr. Wei's failure to apply the methodology that he deems is proper, the Court should exclude his testimony as unreliable. *See Amorgianos*, 303 F.3d at 268-269. Dr. Wei's opinion "rested on a faulty assumption due to his failure to apply his stated methodology 'reliably to the facts of the case.'" *Id*. (internal citations and quotation marks omitted). Expert opinion based on unsubstantiated and undocumented information is "the antithesis of the scientifically reliable

expert opinion admissible under *Daubert* and Rule 702." *Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1423 (9th Cir. 1998).

VI. DR. KURZER IS NOT QUALIFIED TO OFFER OPINIONS RELATED TO COGNITION AND MEMORY

Under Rule 702, courts must determine whether an expert is qualified to offer an opinion based on "knowledge, skill, experience, training, or education." Fed. R. Evid. 702; *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 411-12 (S.D.N.Y. 2016). A witness whose "expertise is too general or too deficient" can be deemed improperly qualified. *Stagl v. Delta Air Lines*, 117 F.3d 76, 81 (2d Cir. 1997). Moreover, under the competent and reliable scientific evidence standard, the evidence offered in support of Prevagen's claims is considered "based on the expertise of professionals in the relevant area." *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186. (*See also* Graham Decl. (ECF No. 225) Ex. F, FTC Guidance at QUI-FTCNY-00189212.) For the Challenged Claims, cognition and memory are the relevant fields of expertise. Because Dr. Kurzer lacks the appropriate expertise in both of these fields, she is not qualified to provide testimony relating to cognition and memory, including on whether the Challenged Claims are supported by competent and reliable scientific evidence.

In her report, Dr. Kurzer offers extensive opinions on topics relating to cognition and memory, including "Cognitive Function and Cognitive Impairment," "Evaluation of Cognitive Function," "Treatment Options for Cognitive Impairment," "Evidence of the Effects of AQ/Prevagen on Brain Function and Memory: *In Vitro* and Animal Studies," and "Evidence of the Effects of AQ/Prevagen on Brain Function and Memory: Human Clinical Studies." (*See, e.g.*, Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report ¶¶ 19-35, 60, 73, 78-80, 83-84.) For example, Dr. Kurzer states that "it has been established that executive functioning, processing speed, and attention all influence memory," "a supplement containing 500-1000

IU/day [of Vitamin D] would be sufficient to achieve cognitive benefits," and the "results of [the Madison Memory Study] suggest that both older adults with [mild cognitive impairment] and those with normal aging-related cognitive decline could benefit from AQ/Prevagen." (*Id.* ¶¶ 35, 80, 83.) Despite offering such opinions, Dr. Kurzer has virtually no experience in cognition or memory.[1] In fact, Dr. Kurzer concedes that she is not an expert in the field of cognitive function. (Matuschak Decl. Ex. D, Kurzer Tr. at 39:9-12.) She does not hold any degrees in any cognition-related field and none of her graduate or postgraduate work involved cognitive function. (*Id*. at 20:2 – 22:24.) Likewise, she has not conducted any clinical trials that involve cognitive function, taught any classes focused on cognitive function, evaluated a person's cognitive function, or used the cognitive assessments given to participants in the Madison Memory Study.[2] (*Id*. at 28:21 – 29:19, 37:22-25, 98:4-20.) Additionally, Dr. Kurzer has neither been involved in any professional organizations that focus on cognitive function, nor written for or edited any academic journals that focus on cognitive function. (*Id.* at 36:19 – 37:15.)

Rule 702 requires that "experts stay within the reasonable confines of their subject area, and cannot render expert opinion on an entirely different field or discipline." *Collado v. City of New York*, No. 11-CIV-9041, 2017 WL 4533772, at *7 (S.D.N.Y. Sept. 27, 2017) (internal quotation marks and citation omitted). "Just because a witness qualifies as an expert with respect to certain matters or areas of knowledge, it by no means follows that he or she is qualified to express expert opinions as to other fields." *Loyd v. United States*, No. 08-CIV-9016, 2011 WL

[1] Dr. Kurzer's limited experience in mood or mental health in connection with diet would not make her qualified to testify about whether Prevagen improves memory or provides other cognitive benefits. (Matuschak Decl. Ex. D, Kurzer Tr. at 28:2 – 31:4).

[2] Dr. Kurzer's mistakes in interpreting the raw scores of two Cogstate measures used in the Madison Memory Study also reflect her lack of knowledge or experience with the measure and the field of cognition generally. (Matuschak Decl. Ex. D, Kurzer Tr. at 215:1 – 221:3).

1327043, at *5 (S.D.N.Y. Mar. 31, 2011) (internal quotation marks omitted). Courts have found experts to be unqualified because they lack knowledge or experience in the relevant field even if they were experts in other scientific areas. *See, e.g.*, *Quintanilla v. Kamori Am. Corp*., No. 07-2375-CV, 2009 WL 320186, at *1-2 (2d Cir. Feb. 10, 2009) (affirming exclusion of an expert who, although a mechanical engineer, had no experience with the printing press at issue or any similar machine); *McCullock v. H.B. Fuller Co.*, 981 F.2d 656, 657 (2d Cir. 1992) (affirming the exclusion of an expert who was an electrical and industrial engineer because he "lack[ed] training or experience in chemical engineering, toxicology, environmental engineering, or the design of warning labels," which was needed to opine on the adequacy of the warning labels at issue); *Trumps v. Toastmaster, Inc.*, 969 F. Supp. 247, 252 (S.D.N.Y. 1997) (holding that a mechanical engineer was not qualified to express an opinion on electrical engineering because the expert was unfamiliar with electrical engineering concepts and therefore could not opine on whether the product's electrical design was defective).

Here Dr. Kurzer's expertise is in nutritional science, which is a field wholly unrelated to cognition. Her experience conducting clinical trials in nutrition or analyzing scientific literature is too general and does not equip her with the necessary knowledge or experience to offer opinions on cognition. *See Stagl*, 117 F.3d at 81 (stating that a court may exclude testimony because the witness' expertise is too general or too deficient); *SEC v. Tourre*, 950 F. Supp. 2d 666, 677 (S.D.N.Y. 2013) (finding that an expert who had a business degree and experience in structured finance was unqualified to testify about collateralized debt obligations because his experience was too general, he had no experience with this type of debt obligation, and he could not speak about industry practices). For example, Dr. Kurzer does not have the appropriate expertise to opine on whether the purported results of the Madison Memory Study were

clinically significant, which is whether the change affects a person's cognitive abilities in a meaningful way. (Soberats Decl. (ECF No. 258) Ex. A, Sano Aff. Report ¶ 37; Matuschak Decl. Ex. D, Kurzer Tr. at 71:23 – 72:8 (stating that clinical significance is different from statistical significance because it relates to a health, disease, or biological endpoint).) Dr. Kurzer admits that a study result can be statistically significant without being clinically significant, that she does not have expertise in clinical significance, and that she does not know whether the purported cognitive benefits reported in the Madison Memory Study were clinically significant. (Matuschak Decl. Ex. D, Kurzer Tr. at 72:9 – 73:8, 198:24 – 200:14, 212:15-20, 228:17-20; *see also* Graham Decl. (ECF No. 225) Ex. F, FTC Guidance at QUI-FTCNY-00189215 (noting that the results of a clinical trial should "translate into a meaningful benefit for consumers" because "[s]ome results that are statistically significant may still be so small that they would mean only a trivial effect on consumer health").) Dr. Kurzer's deficiency of experience or knowledge in cognition renders her unqualified to offer opinions on whether Prevagen causes meaningful improvement in memory or provides other cognitive benefits. *See Loyd*, 2011 WL 1327043, at *5 (excluding testimony because the expert's experience as an internist and infectious disease specialist did not translate to an understanding of the causes of neurological disorders); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp 3d at 439 (finding that although a biomedical engineer was qualified to opine on a mechanism by which the device might perforate a uterus, he was unqualified to opine on the device's effects on uterine tissue because he was not a medical doctor and had no experience in hormonal contraception or the effects of hormones on tissue.)

In determining whether an expert is qualified, courts also consider whether "other experts exist who are more specifically qualified and who are nonetheless not in the employ of the company or industry whose practices are being challenged." *Stagl*, 117 F.3d at 81. Plaintiffs'

expert, Dr. Mary Sano, has extensive education and experience in cognition. For example, Dr. Sano has a Ph.D. in Psychology, is Director of Alzheimer's Disease Research at Mount Sinai School of Medicine, has designed, conducted, and evaluated clinical trials in the areas of cognitive impairment in aging, mild cognitive impairment, and dementia, and published articles related to cognition in more than 200 peer-reviewed publications. (Soberats Decl. (ECF No. 258) Ex. A, Sano Aff. Report ¶¶ 1-10.) In sharp contrast to Dr. Sano, Dr. Kurzer admits that she is not an expert in cognitive function, as evidenced by her lack of knowledge, experience, training, or education in this field, and her opinions are based on scientific literature, which she reviewed solely in preparation for this litigation. *See In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 341 F. Supp. 3d 213, 240 (S.D.N.Y. 2018) (noting that to determine whether an expert has the relevant experience, courts have considered the degree to which that experience was developed for litigation). (*See also* Matuschak Decl. Ex. D, Kurzer Tr. at 87:14 – 99:2.) Dr. Kurzer does not employ the same level of intellectual rigor that characterizes the practice of an expert in the field of cognition. *See In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d at 540.

Because the field of cognition is not within the reasonable confines of her expertise, the Court should exclude Dr. Kurzer's opinions related to cognition and memory, including on whether Prevagen improves memory or provides other cognitive benefits. *See Collado*, No. 11-CIV-9041, 2017 WL 4533772, at *7 ("Rule 702 mandates that experts "stay within the reasonable confines of their subject area, and cannot render expert opinion on an entirely different field or discipline." (internal quotation marks and citation omitted).

VII. DR. KURZER'S ALTERNATIVE ANALYSIS OF THE MADISON MEMORY STUDY SHOULD BE EXCLUDED

Dr. Kurzer's opinion that the Madison Memory Study's results should be evaluated logically is not reliable under Rule 702 and should be excluded. *See In re LIBOR Based Fin.*

Instruments Antitrust Litig., 299 F. Supp. 3d at 467 (stating that an indicia of reliability is whether the testimony is the product of reliable principles and methods). In her report, Dr. Kurzer states that "it is more useful to look at the data [from the nine reported Cogstate measures of the Madison Memory Study] and draw conclusions logically." (Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report ¶ 48.) However, Dr. Kurzer concedes that there are no standards for how to draw conclusions logically and instead relies on her "common sense." (Matuschak Decl. Ex. D, Kurzer Tr. at 204:20 – 207:25.) Dr. Kurzer's own logic or common sense has not been tested, subjected to peer review and publication, subjected to the existence or maintenance of standards controlling its operation, nor has it gained acceptance in the relevant scientific community. *See Amorgianos*, 303 F.3d at 266; *Tramontane v. Home Depot USA, Inc.*, No. 15-CV-8528, 2018 WL 4572254, at *5 (S.D.N.Y. Sept. 24, 2018) (finding that an expert's testimony is unreliable because "there is no scientific methodology on which [the expert's] theory can be tested"). Although Dr. Kurzer states that an approach based on logic is used by others in the nutrition field, she acknowledges that others may apply logic differently and reach different conclusions. (Matuschak Decl. Ex. D, Kurzer Tr. at 207:18-25.) Moreover, because she is not qualified as an expert in cognition or memory, Dr. Kurzer cannot opine on whether logic is used in the relevant fields to determine whether Prevagen improves memory or provides other cognitive benefits.

A method of analyzing data based on just Dr. Kurzer's logic or common sense is unreliable. *See, e.g.*, *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d at 440 (finding the expert's methodology to be unreliable because it was "devoid of objective standards that can be tested by others" and therefore could not be "recreated or reviewed"); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 341 F. Supp. 3d at 247 (finding that without knowing

how the criteria is weighted, a methodology was "virtually standardless and . . . application[] to a particular problem can prove unacceptably manipulable"); *In re Gen. Motors LLC Ignition Switch Litig.*, No. 15-CV-1626, 2017 WL 6729295, at *7 (S.D.N.Y. Dec. 28, 2017) ("An expert's reliance primarily upon his own senses . . . is generally not scientific and does not amount to reliable expert testimony." (internal quotation marks omitted)). For example, Dr. Kurzer originally opined that the results of a particular subgroup showed a benefit for Prevagen because it would be unlikely by chance that seven out of the nine Cogstate tests would have statistically significant results or trend (not statistically significant) in favor of Prevagen. (Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report ¶ 52.) At her deposition, Dr. Kurzer conceded that she had misinterpreted the results for two Cogstate tests and later amended her conclusion to be only five out of nine tests in favor of Prevagen. (Matuschak Decl. Ex. D, Kurzer Tr. at 215:1 – 223:17). However, despite this increase in the number of tests not in favor of Prevagen, her conclusion that this subgroup shows a benefit for Prevagen remained unchanged. (*Id.* at 223:18 – 25:8.) Because Dr. Kurzer is "using [her] logic [and] not using a statistical analysis," there are no parameters or principles to indicate how she analyzed the data, weighed the different the factors, or interpreted the results to draw a conclusion. (Matuschak Decl. Ex. D, Kurzer Tr. at 206:12-13.) Dr. Kurzer's conclusion that there is a benefit associated with Prevagen, based on her logic alone, is unreliable; it is essentially *ipse dixit* and should be excluded. *See Tourre*, 950 F. Supp. 2d at 677 (ruling that expert's opinion based on "economic logic" was inadmissible *ipse dixit* because it was not based on a reliable methodology); *Bocoum v. Daimler Trucks North Am. LLC*, No. 17-CIV-7636, 2022 WL 902465, at *11 (S.D.N.Y. Mar. 28, 2022) (noting that subjective methodology can serve as grounds to reject expert testimony).

VIII. DR. GOODMAN'S TESTIMONY REGARDING POTENTIAL MECHANISMS OF ACTION SHOULD BE EXCLUDED AS UNRELIABLE, IRRELEVANT, PREJUDICIAL, AND OUTSIDE HIS AREA OF EXPERTISE

Defendants propose to present the testimony of Dr. Richard Goodman, a research professor who conducted some laboratory work on apoaequorin, an active ingredient in Prevagen, at Defendants' behest. (*See* Matuschak Decl. Ex. E, Goodman Aff. Report; Matuschak Decl. Ex. F, Goodman Rebuttal Report.) Dr. Goodman purports to be an expert on food allergy, allergenicity, safety of genetically engineered organisms, and food safety in general. (Matuschak Decl. Ex. E, Goodman Aff. Report ¶¶ 6-15.) He intends to present testimony regarding his laboratory study on apoaequorin. Specifically, Dr. Goodman was the principal investigator and author of a report on a study that evaluated apoaequorin's potential allergenicity by testing it *in vitro*. (*See id.* ¶ 19.) As Dr. Goodman confirms, this allergenicity study was designed to determine whether apoaequorin was stable in the presence of pepsin, thus having "a greater probability of causing food allergic reactions." (*See id.* ¶ 34.) Dr. Goodman intends to present testimony that, contrary to the assertions of Plaintiffs' expert, this study cannot be used to show how apoaequorin might be processed in the human digestive system when taken orally – i.e., what happens to apoaequorin when consumers swallow a Prevagen pill. (*See, e.g.*, *id.* ¶ 38 (noting that his *in vitro* study "was not designed to ascertain what digestive products were generated" when apoaequorin was consumed).) Beyond testimony Dr. Goodman might offer as to his conduct of this study and his summary of the results, his testimony would be speculative, unreliable, and prejudicial, and it should therefore be excluded. *See* Fed. R. Evid. 702 (noting that an expert may only be qualified to offer an opinion if the testimony "will help the trier of fact to understand the evidence or determine a fact in issue").

First, Defendants and Dr. Goodman have conceded that his intended testimony is limited to his *in vitro* analysis of apoaequorin. Thus, they have signaled their intent to abandon the

multiple other issues on which Dr. Goodman opines in his expert reports. They should be held to that commitment. Second, Dr. Goodman's proposed testimony goes well beyond the scope of this case. To the extent that Defendants intend to present Dr. Goodman to testify regarding how proteins that are *not* apoaequorin can be absorbed and/or can cause an allergic reaction when consumed orally, such opinions are irrelevant and should be excluded under Rules 402, 403, and 702 of the Federal Rules of Evidence. Third, to the extent that Dr. Goodman purports to opine about the potential absorption or bioactivity of apoaequorin, such testimony is unreliable because (a) he concedes he is not an expert on those topics and (b) he concedes that he has not reviewed or presented evidence on these topics *specific to apoaequorin*. Dr. Goodman's conclusions are therefore both unreliable and outside the scope of his expertise. The Supreme Court has noted that exclusion of expert testimony is warranted where, as here, "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146.

A. Defendants and Dr. Goodman Have Limited the Scope of His Testimony to His Apoaequorin Allergenicity Study

Defendants concede that the point of Dr. Goodman's testimony is that "apoaequorin is non-allergenic and that Plaintiffs are misinterpreting the results of his lab's work." (7/19/22 Letter from Castello to Hon. Louis L. Stanton (ECF No. 286) at 3.) Dr. Goodman confirmed this understanding of the scope of his proposed testimony during his deposition:

> Q. Sorry, but you're here to testify about plausible ways in which apoaequorin, or bioactive products of apoaequorin, could survive digestion and be absorbed.
>
> MR. GRAHAM: Objection.
>
> BY MS. MATUSCHAK: Correct?
>
> MR. GRAHAM: No, objection. I think that's mischaracterizing the scope of Dr. Goodman's report.
>
> THE WITNESS: Yeah. My understanding is I'm here to talk about the stability of the protein in the SGF assay [that I performed on apoaequorin], and really as it

> relates to allergenicity. It is not to say here we have evidence of absorption or bioactivity or whatever. That's not my expertise, and I could only speculate on those things.

(Matuschak Decl. Ex. G, Goodman Tr. at 141:25-142:14.) The portions of Dr. Goodman's report that do not address his laboratory work studying the potential allergenicity of apoaequorin should be excluded from the record and he should be precluded from testifying about those issues at trial.[3]

B. Dr. Goodman's Discussion of Proteins That Are Not Apoaequorin Should Be Excluded as Irrelevant and Prejudicial

Dr. Goodman premises much of his expert reports on a discussion of proteins that have different biological properties from those of apoaequorin. He discusses how these proteins might survive digestion and how they might have a biological effect. He does not, however, make any attempt to determine whether these proteins share the same digestion characteristics as apoaequorin, such that apoaequorin would be expected to perform in the same way in digestion and absorption. His discussion of other proteins should therefore be excluded.

The bulk of Dr. Goodman's discussion of other proteins focuses on proteins that can cause an allergic reaction or a celiac effect. That is not surprising, because allergens and celiac proteins are the focus of his expertise. (*See id.* at 21:20-22.) These proteins are not, however, relevant to the absorption or bioactivity of apoaequorin. As Dr. Goodman has conceded, "the digestion characteristics of apoaequorin are similar to those of common **non-allergenic** dietary proteins." (Matuschak Decl. Ex. G, Goodman Tr. at 95:5-12 (emphasis added).) Because the digestion characteristics of allergenic and non-allergenic dietary proteins differ, and because Dr. Goodman fails to explain how they might be similar or analogous, the digestion characteristics of

[3] The Court should therefore preclude Dr. Goodman from testifying with respect to the issues addressed in Paragraphs 46-79 of his Initial Report and Paragraphs 3-5 and 14-41 of his Rebuttal Report.

allergenic proteins have no bearing on any issue in this case. The pertinent inquiry here is whether apoaequorin, a non-allergenic protein, can have a therapeutic effect on the human body. But Defendants propose to offer Dr. Goodman's testimony as to *allergenic* proteins. As Dr. Goodman concedes, the digestion characteristics of non-allergenic proteins are different from the characteristics of the substances he cites. His discussion of such proteins therefore has no bearing on this case, and should be excluded. Where, as here, a party seeks to admit expert testimony regarding scientific data or studies, the proffered information must "support the conclusions reached," or be excluded. *United States v. Ray*, No. 20 Cr. 110 (LJL), 2022 WL 292800, at *8 (S.D.N.Y. Feb. 1, 2022) (quoting *Amorgianos*, 303 F.3d at 266; *see also Daubert*, 509 U.S. at 591-92 ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.").

For example, Dr. Goodman's report discusses the digestion characteristics of the peanut allergen Ara h 2. (*See* Matuschak Decl. Ex. E, Goodman Aff. Report ¶¶ 68-69, 72; Matuschak Decl. Ex. F, Goodman Rebuttal Report ¶ 16.) Yet Dr. Goodman acknowledged in his deposition that Ara h 2 and apoaequorin have materially different characteristics that would affect their stability in digestion, and he made no effort to explain how the characteristics of Ara h 2 could be analogized to apoaequorin. (Matuschak Decl. Ex. G, Goodman Tr. at 89:15 – 90:19.) Elsewhere, Dr. Goodman's report discusses the absorption of celiac peptides (*see* Matuschak Decl. Ex. E, Goodman Aff. Report ¶ 48), but at his deposition he conceded that he is not aware of apoaequorin producing such peptides (Matuschak Decl. Ex. G, Goodman Tr. at 105:10-25.) Indeed, Dr. Goodman made clear that he was not using his discussion of allergens to draw any conclusions whatsoever about apoaequorin. (*Id*. at 200:1 – 201:13.) Testimony regarding these other proteins would accomplish nothing more than jury confusion. *See, e.g.*, *Aiyer*, 33 F.4th at

126 (upholding district court's exclusion of expert testimony under Rules 702 and 403 where it would have risked "clouding" the determinations at issue "and would have potentially confused or misled the jury") (internal quotation marks omitted); *United States v. Litvak*, 808 F.3d 160, 185-86 (2d Cir. 2015) (upholding exclusion of expert testimony where "potential confusion from such testimony might have outweighed any probative value"); *United States v. Ray*, 2022 WL 292800, at *14 (excluding expert testimony in light of "distinct danger" it would confuse jury).

Dr. Goodman's discussion of proteins that are not apoaequorin also includes proteins that are found in breast milk. First, most, if not all, such proteins discussed by Dr. Goodman are allergens, which apoaequorin is not. Second, Dr. Goodman was unaware of proteins that digest as rapidly as apoaequorin that made it into the bloodstream or into breast milk. (Matuschak Decl. Ex. G, Goodman Tr. at 132:24 – 133:11.) Third, Dr. Goodman fails to explain why the appearance of allergens in breast milk would indicate that a non-allergen would appear in the brain. Testimony regarding *other* proteins being found in breast milk would be so far afield of the issues in this case that it would result in a trial within a trial about the absorption of substances that are simply not at issue. Courts routinely exclude expert testimony where a party seeks to draw a comparison with scientific phenomena or studies only tenuously related to the relevant inquiry. *See, e.g.*, *In re Fosamax Products Liability Litigation*, 645 F. Supp. 2d 164, 198 (S.D.N.Y. 2009) (excluding proffered expert testimony as to "supposed similarities" between medical condition at issue, which was associated with a certain substance, and a separate medical condition associated with a related substance, where proffered testimony failed to establish an adequate link between the two conditions, such that its probative value would be "substantially outweighed by the corresponding waste of time, danger of confusion, and unfair prejudice"); *United States v. W.R. Grace*, 455 F. Supp. 2d 1181, 1191-94 (D. Mont. 2006) (in

case where defendant was indicted in connection with alleged release of asbestos, excluding prosecution study showing correlation between certain health effects and certain "pathways" of asbestos exposure, where proffered study was materially distinguishable and there was a risk jury would give it "undue weight").

C. Dr. Goodman Lacks the Expertise to Testify About the Absorption or Bioactivity of Apoaequorin

Dr. Goodman purports to be an expert on food allergy, allergenicity, safety of genetically engineered organisms, and food safety in general. (Matuschak Decl. Ex. E, Goodman Aff. Report ¶¶ 6-15; *see also* Matuschak Decl. Ex. G, Goodman Tr. at 21:20 – 22:13, 22:14 – 23:2.) He conceded that he is not an expert on protein absorption outside the context of allergens and celiac peptides. (*Id*. at 36:1-8, 36:15-19; *see also id.* at 215:5-6 ("I'm not an expert in absorption of different proteins and peptides").) He also conceded that, outside the context of safety, food, and potential allergenicity, he is not an expert on biochemistry as it relates to "how each protein is folded or produced or what it will do . . . ." (*Id*. at 39:13 – 40:1.) He specifically confirmed that whether apoaequorin could have a therapeutic or bioactive effect was outside his expertise. (*Id*. at 224:20 – 225:6.) Finally, he conceded that apoaequorin is neither an allergen nor a celiac gluten peptide, nor does it digest into celiac gluten peptides. (*Id*. at 88:10-11, 103:16-23, 105:1-9, 153:5-7.) Dr. Goodman therefore does not have expertise to opine about how apoaequorin might be absorbed or how it might have a biological effect in humans, and he should be precluded from testifying about these issues. *See Quintanilla*, 2009 WL 320186, at *1-2 (affirming exclusion of expert testimony where witness lacked the relevant expertise).

D. Dr. Goodman Should Be Precluded From Offering Speculative Testimony About Potential Mechanisms of Action

Dr. Goodman's reports speculate about how apoaequorin might work, but they are bereft of any scientific reasoning or evidence tied to analysis of apoaequorin. As noted above, Dr.

Goodman is not qualified to discuss how apoaequorin might work. Even if he were, his testimony is so speculative that the jury should be shielded from it. *See Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996) (noting that "expert testimony should be excluded if it is speculative or conjectural"). For example, Dr. Goodman discusses "bioactive peptides" – the concept that some peptides that remain following protein digestion might have some physiological function. (Matuschak Decl. Ex. E, Goodman Aff. Report ¶¶ 63-65.) He conceded, however, that he did not determine what products of apoaequorin might exist following digestion. (Matuschak Decl. Ex. G, Goodman Tr. at 140:19 – 141:2.) He thus could not opine on whether apoaequorin, following digestion, produces amino acids, peptides, or both, and if so, whether they share the characteristics of peptides that he identifies as "bioactive." To permit speculative testimony about bioactive peptides based solely on observations regarding other proteins, without tying those observations to the characteristics of apoaequorin, would be leading the jury down a path that is based on conjecture, not science. Such testimony should be excluded. *See In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d at 198.

IX. DR. GORTLER'S TESTIMONY SHOULD BE EXCLUDED IN ITS ENTIRETY

Defendants also intend to present the testimony of a pharmacologist, Dr. David Gortler, in rebuttal to testimony anticipated by one of Plaintiffs' experts, Dr. Jeremy Mark Berg. (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶ 2.) Dr. Gortler conceded that the main point of his testimony is the (unremarkable) proposition that a mechanism of action need not be known in order for a drug or dietary supplement to work. (*Id.* ¶ 37.) Dr. Gortler also argued that a mechanism of action need not be known for a drug to obtain FDA approval. (*Id.* ¶ 38.) Dr. Berg never asserted that a mechanism of action need be known for a drug or supplement to work, nor did he assert anything about FDA requirements. Therefore, this testimony would be improper rebuttal and should be excluded on that basis. *See ProBatter Sports LLC v. Sports Tutor, Inc.*,

No. 3:05-cv-10975, 2020 U.S. Dist. LEXIS 257178, at *7 (Aug. 21, 2020) (precluding rebuttal expert from testifying regarding non-rebuttal issues). The remaining testimony Dr. Gortler wishes to present is premised on points that are irrelevant to the case or, at a minimum, would serve to mislead the jury and waste its time. Dr. Gortler should therefore be precluded from testifying.

A. Dr. Gortler's Discussion About Other Drugs That Work, and Unsupported Speculation That Apoaequorin Might Work, Should Be Excluded

Much of Dr. Gortler's opinion focuses on drugs and substances other than apoaequorin that have an effect on the body, some of which have a known mechanism of action and some of which do not. Yet he never ties these discussions to any property of apoaequorin. Indeed, he noted in his deposition, "I haven't done any clinical or analytical analyses whatsoever on apoaequorin, Prevagen, et cetera." (Matuschak Decl. Ex. I, Gortler Tr. at 31:7-9.) Testimony regarding drugs or supplements that are *not* Prevagen, without addressing whether such drugs or supplements have similar properties to Prevagen, would be irrelevant and therefore waste the jury's time; would confuse the issues presented to the jury; and would be prejudicial. For these reasons, these opinions should be excluded.

Dr. Gortler opined at length about a number of substances that are not apoaequorin, but he made no effort to determine if they have any similarities to apoaequorin. For example, his expert report discusses a number of prescription prodrugs, which he defines as "compounds that are inactive in their parent form but following metabolism are chemically transformed into an active drug." (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶ 45.) Yet Dr. Gortler does not cite evidence that apoaequorin is a prodrug, and he conceded at his deposition that – as far as he knew – none of the prodrugs he cited was even a protein, peptide, or amino acid. (Matuschak Decl. Ex. I, Gortler Tr. at 106:19 – 107:6.) Nor were any of those prodrugs used to treat memory

or cognition. (*Id*. at 107:7-10.) Similarly, Dr. Gortler discusses microorganisms that, despite their large size, can survive in the stomach. (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶ 58.) However, none of these microorganisms is a protein or peptide, and Dr. Gortler could not opine about their size, apoaequorin's size, or Prevagen's size. (Matuschak Decl. Ex. I, Gortler Tr. at 123:6 – 125:7.) Indeed, Dr. Gortler was unable to draw an analogy between these microorganisms and apoaequorin. Testimony about these substances is therefore irrelevant to this case. To the extent that Dr. Gortler seeks to use these substances to establish a mechanism of action for apoaequorin, he has failed to explain how apoaequorin shares characteristics with these substances that would cause the same effects. His testimony, therefore, is irrelevant and should be excluded. *See Boucher*, 73 F.3d at 21 (noting expert testimony should be excluded if it is "in essence an apples and oranges comparison") (internal quotation marks and citation omitted); *see also In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d at 198; *Borsack v. Ford Motor Co.*, No. 04 Civ. 3255 (PAC), 2009 WL 5604383, at *1-3 (S.D.N.Y. Feb. 3, 2009) (excluding as irrelevant expert testimony regarding mechanism of product that had "substantial differences" with product at issue).

B. Dr. Gortler's Discussion of FDA Requirements With Respect to Dietary Supplements Should Be Excluded as Irrelevant

Dr. Gortler opines that the FDA does not require dietary supplements to have a known mechanism of action, and that the FDA does not regulate dietary supplements. (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶¶ 38, 89.) This testimony is irrelevant to any issue in the case and should be excluded. FDA regulation does not have any impact on the issues for the jury to decide, which relate to whether Defendants' advertising claims were permissible under the FTC Act and New York consumer protection statutes. *See supra* Section III.A. Thus, Dr. Gortler's

statements on what the FDA requires are irrelevant to any issue in this case and should be excluded.

C. Dr. Gortler's Discussion of Calcium's Role in Memory and Alzheimer's Disease Should Be Excluded as Irrelevant and Unreliable

Defendants argue that Prevagen is not intended to treat any disease, yet they seek to present extensive expert testimony from Dr. Gortler regarding Alzheimer's disease, noting that "Dr. Gortler's discussion of Alzheimer's disease linked a cause of memory loss (excess calcium) and apoaequorin's efficacy (its ability to bind and reduce calcium)." (7/19/22 Letter from Castello to Hon. Louis L. Stanton (ECF No. 286).) This purported relationship assumes that apoaequorin is effective because it binds and reduces calcium *in the brain*[4] – a theory that Defendants once advanced and then abandoned, at least when it suited their position before the FDA. (*See* Matuschak Decl. Ex. D, Kurzer Tr. at 278:17-23 (describing the calcium binding theory as one of the "original hypotheses"); Matuschak Decl. Ex. J, Schwartz Tr. at 256:19 – 257:7 (noting that the apoaequorin calcium-binding theory was "one school of thought that was more prevalent, I think, earlier").) Indeed, Defendants argued in a submission to the FDA, citing Dr. Goodman's allergenicity study, that "following oral consumption by humans, Apoaequorin is likely to be completely hydrolyzed to individual amino acids that will be absorbed in a process similar to other dietary proteins." (*See* Soberats Decl. Ex. L, Berg Aff. Report ¶ 29.) Moreover, Dr. Gortler conceded, in order to improve memory and cognition through calcium-binding, apoaequorin must be present in the brain:

> Q. . . . One of the possible ways that [apoaequorin] improves memory and cognition is through calcium-binding. Is that your opinion?
>
> A. Yes.

[4] Although Dr. Gortler's discussion of calcium ventures well beyond apoaequorin, his *apoaequorin*-specific calcium discussion relates to apoaequorin's effect on the brain. (*See* Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶¶ 63-68, 79-80.)

> Q. And in order to have an effect on memory or cognition through calcium-binding, apoaequorin would need to be present in the brain; is that correct?
>
> A. Yes.

(Matuschak Decl. Ex. I, Gortler Tr. at 86:24 – 87:7.)[5] Defendants have likewise confirmed that apoaequorin is unlikely to pass through the gastrointestinal tract intact.[6] As such, apoaequorin cannot reach the brain and therefore cannot have a therapeutic, calcium-binding effect on brain cells.

Defendants' other experts agree that orally administered apoaequorin is unlikely to enter the bloodstream and cross the blood-brain barrier. Indeed, one of Defendants' current experts has offered the opinion that "it is unlikely that intact [apoaequorin] is absorbed and enters the brain." (*See* Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report ¶ 56.) Another of Defendants' experts testified that the concept of apoaequorin breaking down into amino acids in the gastrointestinal tract "makes sense." (Matuschak Decl. Ex. J, Schwartz Tr. at 260:7-18.) Indeed, the evidence Dr. Gortler cites in support of apoaequorin having some positive effect on brain cells is based on a rat study in which apoaequorin was injected directly into their brains – not consumed orally, as Prevagen is. (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶ 84.)

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[5] Dr. Gortler did speculate that Prevagen's "substrates and/or its metabolites may exert pharmacological activity through calcium signal binding cites" (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶¶ 41, 91), but this speculation was not backed by any evidence specific to apoaequorin. (*See* Matuschak Decl. Ex. I, Gortler Tr. at 103:23 – 104:22.) This speculative testimony is inadmissible. *See Boucher*, 73 F.3d at 21.

[6] Defendants have presented a brand new theory in Dr. Gortler's rebuttal report – that apoaequorin could somehow cross the blood-brain barrier through cholesterol binding. This position is inconsistent with the positions taken by Defendants' other experts. And, as discussed in the next section, this testimony should be excluded because it is speculative, based on hearsay, not based on Dr. Gortler's independent analysis, and because at his deposition, Dr. Gortler could not answer the most basic questions about his sources.

Because Dr. Gortler has failed to explain why orally consumed apoaequorin would have the same effect on human brain cells as apoaequorin injected into a rat's brain, this testimony should be excluded as unreliable. *Cf. Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1484-85 (D.V.I. 1994), *aff'd without opinion,* 46 F.3d 1120 (3d Cir.1994) (excluding expert testimony purporting to show a link between the drug at issue and certain birth defects, where the testimony "ignore[d] the question of therapeutic dosage," even though the "core issue" was whether the drug caused defects "at therapeutic doses," such that expert's testimony would likely "confuse, mislead and overwhelm the jury").

Simply put, Dr. Gortler's discussion of Alzheimer's disease and calcium signaling is unreliable, irrelevant, and his testimony would be confusing and therefore prejudicial. The pathology of Alzheimer's disease has no bearing on whether Prevagen can improve memory and cognition in healthy adults. It does not have "any tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401. Defendants should not be permitted to present such confusing information to the jury, particularly where, as here, the testimony is directly at odds with Defendants' own admissions.

D. Dr. Gortler's Speculative "Active Transport" Testimony Should Be Excluded as Unreliable

Dr. Gortler speculates that consuming apoaequorin together with dietary cholesterol "has the potential to 'greatly facilitate' the uptake of intact protein from the gut." (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶ 64.) This testimony should be excluded as unreliable. Dr. Gortler made clear at his deposition that he does not possess the knowledge or expertise to testify regarding this mechanism of action theory, and review of literature alone does not qualify one as an expert, particularly where, as here, the literature in question is not understood by the expert. *See Wade-Greaux*, 874 F. Supp. at 1476 (noting that review of selected literature did not qualify

witness to testify as an expert). Dr. Gortler is merely serving as a vehicle to attempt to present hearsay material regarding an analysis he did not conduct and could not explain. For example, when asked how the consensus sequence used in the cited reference was discovered, Dr. Gortler said, "You'd have to ask the authors of the article." (Matuschak Decl. Ex. I, Gortler Tr. at 135:5-8.) Additionally, Dr. Gortler presented a figure in his report that purported to identify cholesterol-binding sites that allegedly "assist with active transport into the blood stream or into the brain." (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶ 65.) Dr. Gortler confirmed that this figure was taken verbatim out of a publication and did not represent his own analysis predicting cholesterol-binding sites. (*See* Matuschak Decl. Ex. I, Gortler Tr. at 134:3-24.) When asked if the "X" in the figure he copied into his report could stand for any amino acid, Dr. Gortler said:

> A. I don't know. I would refer to the peer reviewers who wrote this out. If it was done by some kind of questionable technology or some kind of questionable methodology, I would leave that for the – for either the authors or the peer reviewers to say something.

(*Id.* at 139:24 – 140:6.) Dr. Gortler could not answer specific, basic questions about the methodology used to draw conclusions about cholesterol binding, noting that he is not an expert in that scientific methodology. (*See, e.g.*, *id.* at 134:3 – 139:19.)

Experts cannot be used as a vehicle to introduce hearsay evidence just by having them quote a reference they do not understand. *See Au New Haven v. YKK Corp.*, No. 15-cv-3411, 2019 U.S. Dist. LEXIS 45044, at *30 (S.D.N.Y. Mar. 19, 2019) (noting that "parties . . . cannot use experts as a Trojan Horse of hearsay"); *Rotman v. Progressive Ins. Co.*, 955 F. Supp. 2d 272, 283 (D. Vt. 2013) (noting that it is "appropriate for district courts to recognize the risk that a particular expert might become nothing more than a transmitter of testimonial hearsay and exercise their discretion in a manner to avoid such abuses") (citation omitted). For these reasons,

Dr. Gortler should be precluded from testifying about the issues raised in paragraphs 63-68 of his expert report.

E. Dr. Gortler Should Be Precluded From Opining About the Madison Memory Study

Dr. Gortler opines about the Madison Memory Study in his rebuttal report. (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶¶ 86-88.) But at his deposition, he made clear that he did not intend to offer that opinion at trial in this matter. (Matuschak Decl. Ex. I, Gortler Tr. at 44:11-13 ("I wasn't asked to give an opinion on the Madison Memory Study, and I don't have an opinion."), 180:11-22 (noting that he is not prepared to offer an opinion on the Madison Memory Study other than that his report "just, for lack of a better word, parroted some of the sections of the study itself").) Dr. Gortler, therefore, should be precluded from offering any opinion regarding the Madison Memory Study.

F. Dr. Gortler Should Be Precluded From Testifying That Prevagen is Safe

Dr. Gortler opines that Prevagen is safe. (Matuschak Decl. Ex. H, Gortler Rebuttal Report ¶¶ 78, 88-89.) Such testimony is not relevant to any issue in this case, which is about whether Defendants' advertising claims for Prevagen are substantiated. Testimony regarding the purported safety of Prevagen would distract the jury and waste its time considering an issue that has nothing to do with substantiation of advertising claims. Emphasis on the conclusion that Prevagen is safe would create the illusion that there is some legitimacy to Defendants' advertisements of their products. It should therefore in the alternative be excluded under Rule 403.[7] *See Luitpold Pharms., Inc. v. ED. Geistlich Soghne A.G. Fur Chemische Industrie*, No.

[7] Drs. Katz, Schwartz, and Kurzer also state that Prevagen and/or apoaequorin are safe. For the same reasons, their testimony on safety should also be excluded. (Graham Decl. (ECF No. 225) Ex. O, Katz Aff. Report ¶ 14; Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report ¶ 36; Graham Decl. (ECF No. 225) Ex. W, Schwartz Aff. Report ¶¶ 59-61.)

11-cv-681, 2015 U.S. Dist. LEXIS 123591, at *20 (S.D.N.Y. Sept. 16, 2015) (in precluding expert testimony, noting that because the proposed testimony was "untethered to the contractual standard at issue," it was "unhelpful and misleading to the trier of fact" and that "[a]ny probative value in the opinions is substantially outweighed by the danger that the jury would be seriously misled").

X. DRS. KURZER, SCHWARTZ, AND KATZ SHOULD BE PRECLUDED FROM TESTIFYING REGARDING APOAEQUORIN'S POTENTIAL MECHANISMS OF ACTION

Drs. Kurzer, Schwartz, and Katz each purport to opine regarding potential mechanisms of action for apoaequorin, but their testimony is not actually tied to apoaequorin and is far too speculative to be of value to the jury. (Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report ¶¶ 54-57; Graham Decl. (ECF No. 225) Ex. W, Schwartz Aff. Report ¶¶ 13, 17, 56-64, 69-75, 78-79; Graham Decl. (ECF No. 225) Ex. X, Schwartz Rebuttal Report ¶¶ 21, 27-36; Graham Decl. (ECF No. 225) Ex. O, Katz Aff. Report ¶¶ 10-14, 67-70; Graham Decl. (ECF No. 225) Ex. P, Katz Rebuttal Report ¶¶ 3, 6-8, 11-17.) Given their experts' widely varying, and sometimes contradictory, opinions, it appears that Defendants do not intend to present a unified theory about Prevagen's mechanism to the jury. Rather, it appears they intend to throw a series of speculative theories at the jury in hopes that the confusion will create the illusion that there is something relevant in this mess. There is not. Each of these experts concedes that the mechanism of action for apoaequorin is not known, a fact that is undisputed in this case. Each of these experts then offers speculation about how apoaequorin might cause an effect based on how other substances work, without ever tying that speculation to any characteristic of apoaequorin. The fact, for example, that a seaweed extract has a therapeutic effect on the body, even though nobody knows how it works, does not make it any more likely that apoaequorin would have an effect on memory or cognition – unless one can point to some similarity between the seaweed extract and

apoaequorin. They instead cite numerous other substances that do not share characteristics with apoaequorin, and speculative theories that are not based on evidence related to apoaequorin. Defendants should not be permitted to waste the jury's time with this confusing and irrelevant testimony. *See Boucher*, 73 F.3d at 21 (noting expert testimony should be excluded if it is based on unrealistic and contradictory assumptions) (citing *Shatkin v. McDonnell Douglas Corp.*, 727 F.2d 202, 208 (2d Cir. 1984)).

A. Dr. Kurzer's Proposed Mechanism of Action Testimony is Unreliable, Irrelevant, and Prejudicial

Dr. Kurzer acknowledges that the mechanism of action for Prevagen is not known. (Graham Decl. (ECF No. 225) Ex. R, Kurzer Rebuttal Report ¶ 56.) She then goes on to discuss mechanisms by which substances *other than apoaequorin* have an effect on the brain, either through the so-called "gut-brain axis" or by creating so-called "bioactive peptides." (*Id.* ¶¶ 56-57.) Dr. Kurzer concedes that she cites zero evidence tying either of these mechanism theories to apoaequorin. (*See* Matuschak Decl. Ex. D, Kurzer Tr. at 285:20 – 286:14, 288:18-21, 289:17-21.) Her proposed testimony therefore is too tangential, and too speculative, to assist the jury in making any finding that is relevant to this case. It should be excluded. *See Mancuso v. Consolidated Edison Co.*, 967 F. Supp. 1437, 1441 (S.D.N.Y. 1997) (citing Second Circuit requirement "that expert testimony should be excluded if it is speculative or conjectural") (citing *Boucher v. Suzuki*, 73 F.3d 18, 21) (2d Cir. 1996)). Even if the Court were to deem Dr. Kurzer's proposed mechanism testimony somehow relevant, its use would confuse the jury and be more prejudicial than it is helpful. Speculative testimony about the gut-brain axis and bioactive peptides would necessarily imply that those mechanisms are relevant to apoaequorin, but none of Defendants' experts have presented evidence that they are.

B. Dr. Schwartz's Proposed Mechanism of Action Testimony is Unreliable, Irrelevant, and Prejudicial

Dr. Schwartz, like Defendants' other experts, attempts to create the illusion of a known mechanism of action by talking about other drugs as well as the gut-brain axis theory – all without tying any of these to any evidence related to apoaequorin. (Graham Decl. (ECF No. 225) Ex. W, Schwartz Aff. Report ¶¶ 13, 17, 62, 71-75; Graham Decl. (ECF No. 225) Ex. X, Schwartz Rebuttal Report ¶¶ 28-30, 31-33.) For the reasons stated above, testimony regarding other drugs, and regarding the gut-brain axis, is irrelevant and prejudicial.

Dr. Schwartz's only proposed testimony tied directly to *apoaequorin's* mechanism of action is the calcium-binding theory. (Schwartz Report ¶¶ 13, 17, 62, 79.) As with Dr. Gortler's discussion of the calcium-binding theory, Dr. Schwartz's discussion is premised on Defendants' old mechanism of action theory – that apoaequorin has a therapeutic effect by binding to calcium in brain cells. (*See* Matuschak Decl. Ex. J, Schwartz Tr. at 255:4-18 (noting that his calcium-binding theory was advanced by "Quincy investigators and Quincy scientists").) Defendants have since abandoned that theory, including in Dr. Kurzer's expert report. (*See* Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report ¶ 56.)

Ultimately, Dr. Schwartz conceded that the only reason he discussed potential mechanisms of action at all was to point out that a mechanism of action does not need to be known in order for a drug to work. (*See, e.g.*, Matuschak Decl. Ex. J, Schwartz Tr. at 265:14 – 266:3.) The fact that there are some substances out in the world that can have an effect on the human body without a known mechanism of action does not make it more or less likely that Defendants' claims about Prevagen are substantiated. Such testimony is therefore irrelevant and should be excluded under Rule 402. The potential danger of Dr. Schwartz's testimony is made clear through his discussion of oligomannate, a seaweed extract that was purportedly approved to

treat mild to moderate Alzheimer's disease in China in 2019. (Graham Decl. (ECF No. 225) Ex. W, Schwartz Aff. Report ¶ 63.) Dr. Schwartz's report stated, "it is noteworthy that oligommanate may have a similar mechanism of action to that of Prevagen . . . ." (*Id.*) When asked about this statement at his deposition, Dr. Schwartz explained:

> Q. Well, you say here that "oligomannate may have a similar mechanism of action to that of Prevagen." What did you mean by that?
>
> A. It's somewhat speculative. It's somewhat speculative. I'll admit that. It's just that we don't know really how either compound works, and both compounds have evidence of benefit in cognitive functioning. And for all we know, they could have similar mechanism of action, but I don't know that.

(Matuschak Decl. Ex. J, Schwartz Tr. at 264:8-18.) Such speculative testimony, not grounded in any science or evidence, would at best waste the jury's time and at worst confuse them into thinking a non-protein seaweed extract has the same function as Prevagen. There is simply no evidence to support that speculation. That oligommanate might work to treat Alzheimer's disease has no bearing on whether apoaequorin can improve cognition in normal adults. This testimony therefore should be excluded.

C. Dr. Katz's Proposed Mechanism of Action Testimony is Unreliable, Irrelevant, and Prejudicial

Defendants present Dr. Katz as yet another expert to offer speculation about apoaequorin's mechanism of action. Dr. Katz, however, confirmed at his deposition that he is "not personally taking a position on the specific mechanism that is actually responsible for [apoaequorin's] effects." (Matuschak Decl. Ex. A, Katz Tr. at 235:13-15.) Speculation about how apoaequorin *might* work has no relevance to this case and no value for the jury.

One element of Dr. Katz's speculative testimony is based on the calcium-binding theory. (*See* Graham Decl. (ECF No. 225) Ex. O, Katz Aff. Report ¶¶ 11-13, 67-68; Graham Decl. (ECF No. 225) Ex. P, Katz Rebuttal Report ¶¶ 7-8.) However, Dr. Katz concedes that he does not

know how probable it is that apoaequorin actually has an effect through calcium-binding. (S*ee* Matuschak Decl. Ex. A, Katz Tr. at 235:16-20.) He also concedes that he does not know whether, for the calcium-binding effect to work, intact apoaequorin has to be present in the brain. (*See* Matuschak Decl. ¶ A, Katz Tr. at 235:22 – 236:5.) Dr. Katz notes that his knowledge that apoaequorin is a calcium-binding protein was not based on any independent analysis, but rather the suggestion of others who had studied apoaequorin (i.e., Defendants and those commissioned by them). (*See id.* at 235:1-9.) He goes on to speculate that derivatives of a compound might exert the same effect as the intact compound, but he concedes that he has no knowledge of whether derivatives of apoaequorin can have the same effect as apoaequorin. (*Id.* at 236:6-14.)

Dr. Katz, like other of Defendants' experts, also suggests that Prevagen might somehow work via the gut-brain axis. (Graham Decl. (ECF No. 225) Ex. O, Katz Aff. Report ¶ 69.) Following a general discussion about influences that the human gastrointestinal tract might have on the central nervous system, Dr. Katz concludes, "Substances like probiotics, proteins, and peptides may influence the balance and diversity of the microbiome in ways that impact cognitive performance." (*Id.*) This conclusion is not tied to apoaequorin in any way, nor is it relevant to whether or not these unspecified substances do, or are likely to, have an impact on cognitive performance. The jury should not have to hear it.

Finally, Dr. Katz also proposes to discuss other substances, which are not apoaequorin, for which the mechanism of action is not known. (*Id.* ¶ 70.) The fact that an unknown mechanism of action does not preclude a finding of efficacy is not a disputed fact in this case. Permitting discussion of other substances for which a mechanism of action is not known would be a waste of the jury's time and prejudicial to the extent that it suggests these substances bear some relationship to apoaequorin. Dr. Katz does not suggest that they have such a relationship.

For the foregoing reasons, Dr. Katz's testimony regarding mechanism of action should be excluded in its entirety.

XI. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the testimony of Defendants' experts.

Respectfully submitted,

Dated: September 1, 2022

FEDERAL TRADE COMMISSION

/s/ Andrew Wone
ANNETTE SOBERATS
EDWARD GLENNON
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CERTIFICATE OF SERVICE

I certify that on this 1st day of September 2022, I caused service of the foregoing Plaintiffs' Memorandum of Law in Support of Their Motion to Exclude the Testimony of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler to be made by electronic filing with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record.

Dated: September 1, 2022

/s/ Annette Soberats
Annette Soberats
Federal Trade Commission